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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/314,919	05/19/1999	WILLY MICHEL	6464	5806

25763 7590 10/23/2003

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INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

MENDEZ, MANUEL A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/314,919

Applicant(s)

MICHEL ET AL.

Examiner

Manuel Mendez

Art Unit

3763

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-17,21-24,27-40,42-54 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,12-17,21-24,27-40, 42-54, and 56-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

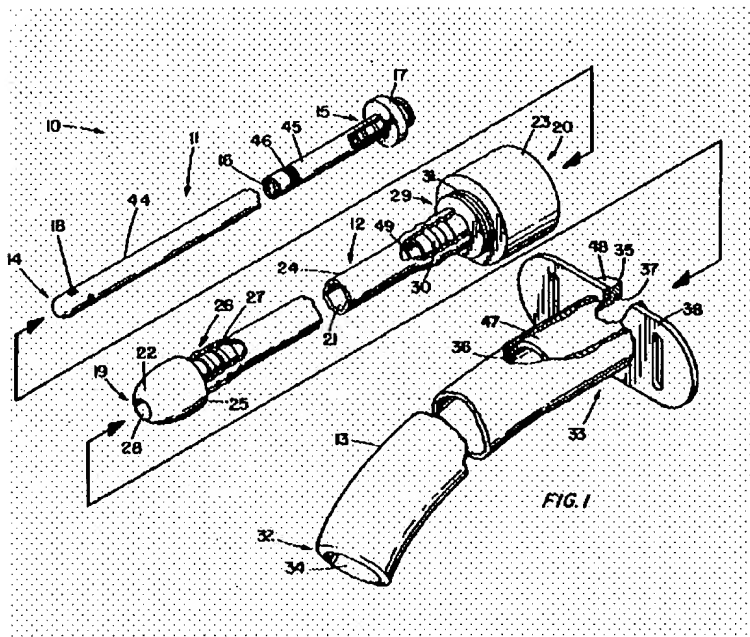
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

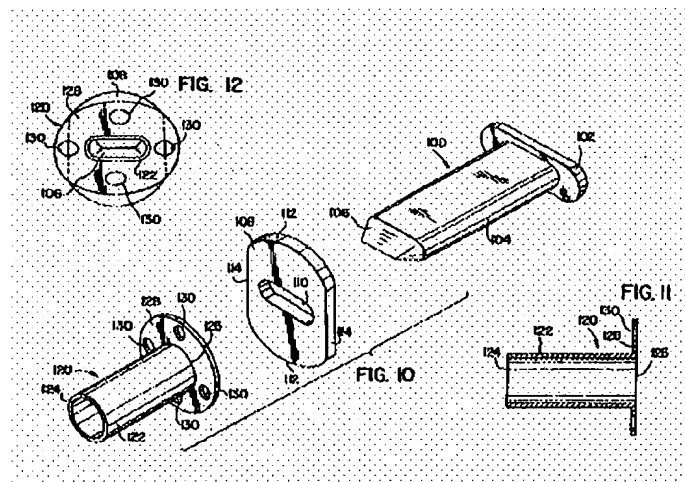
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 12-17, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bestetti, et al.**¹, **Baudino, or Schafer, et al.**, in view of **Park, et al.**, or **Hildwein, et al.** According to applicant's remarks, neither Bestetti, et al., Baudino, nor Schafer, et al., discloses "that any device travels through the catheter". However, the insertion of a device or instrument through an implanted catheter or tubular implanted device is conventional as demonstrated by the teachings of Park, et al., or Hildwein, et al.

¹ U.S. Patent Number 6,270,475.



In figure 1, **Park, et al.**, demonstrates the conventionality of inserting an instrument through an implanted catheter.



Additionally, figure 10 of **Hildwein, et al.**, demonstrates the conventionality of inserting an instrument through an implanted catheter. Based on the above observations, it would be obvious for a person of ordinary skill in the art to enhance the inventions of **Bestetti, et al.**, **Baudino**, or **Schafer, et al.**, with the capability for the insertion of

surgical instruments. Conclusively, such enhancement would be considered an obvious design alternative.

Claims **27-39, 40, 42-54, and 56-62** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuschieri, et al., in view of Park, et al., in view of Donaldson, et al., or Patsalos, et al.

In response to applicant's arguments, the examiner of record has withdrawn Schafer, et al., as utilized in the last office action in the section 103 rejection. Concerning Donaldson, et al., the applicant concluded that said patent was nonanalogous art to the other references in the rejection. However, the examiner of record respectfully disagrees. Introductory ports are used extensively in the medical arts as a medium between the exterior and interior of the body. Regardless of the area of application, introductory ports require a space within the surface of the body for the introductory port to be inserted in. Arguably, whether the space is a natural body orifice, like the ear canal, or a space created by an obturator/cutter, the requirement for an "insertion space" is the same. Therefore, the examiner concludes that "natural orifice" introducers should be considered analogous to "body incision" introducers.

In relation to the section 103 rejection above, Cuschieri, et al., discloses an access port with an elastic self-closing diaphragm for accessing the interior of the body. Cuschieri, et al., does not disclose a multi-lumen structure or the use of sensors. However, Park, et al., demonstrates that it is conventional in the art to introduce medical devices through implanted catheters. Additionally, Donaldson, et al., and Patsalos, et

al., demonstrate the conventionality of multi-lumen introducers and the use of sensors in combination with introducers.

Based on the above observations, it would be obvious for a person of ordinary skill in the art to modify Cuschieri, et al., by re-designing the introducer with separate lumens as Donaldson, et al., teaches and with the capability of use with a sensor or probe as Patsalos, et al., demonstrates in its specification. Accordingly, a person of ordinary skill in the art would consider such enhancements as obvious design alternatives.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

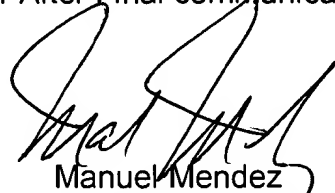
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.



Manuel Mendez
Primary Examiner
Art Unit 3763

October 20, 2003